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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/059,627	01/29/2002	Yawei Ni	103216.00252 (CARR-0084)	5288

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EXAMINER	
MELLER, MICHAEL V	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/059,627	NI ET AL.	
	Examiner	Art Unit	
	Michael V. Meller	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5,7,13-15,17 and 23-25* is/are pending in the application.

4a) Of the above claim(s) *2, 4, 6, 8-12, 16, 18-22, 26-77* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5,7,13-15,17 and 23-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 5, 7, 13-15, 17, 23-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for KGF and plasminogen or plasmin, does not reasonably provide enablement for any and all growth factor proteins and proteases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The specification as filed, is enabled for KGF and plasminogen or plasmin, but is not enabled for any and all growth factor proteins and proteases.

The art of biotechnology is a highly unpredictable art and it would be an undue burden for one of ordinary skill in the art to test any and all proteases and growth factors to see if they would yield the alleged unexpected results. Applicants themselves have argued in their previous response the criticality of the claimed combination of KGF and plasmin or plasminogen (see page 13, first full paragraph of the brief filed 6/6/2005). If

any growth factors and proteases were so well known to be combined, why would applicants emphasize that the prior art does not teach the specifically claimed combination of KFG and plasminogen or plasmin and submit that unexpected results were found with that specific combination if it was so well known to do so. If it was so well known to do so, it would be clear from the prior art that such is the case, but the reverse is true. There is no prior art known to this examiner that establishes that one of ordinary skill in the art would have known at the time the invention was made that such a specific combination of KGF and plasminogen or plasmin would yield such unexpected results otherwise it would have turned up in the prior art search and used against the instant claims.

Applicant has only shown in their examples one source of the claimed growth factor (KGF) and only plasminogen and plasmin as the proteases. With only knowing these specific growth factor and two enzymes it is clear that such broad claims are not enabled by the instant specification when one of ordinary skill in the art is only given one particular growth factor and two specific enzymes from which to arrive at the specifically claimed composition which yields such unexpected results. Applicants claims are not commensurate in scope with their alleged unexpected results. To test any and all proteases and growth factors to see if they would yield such unexpected results is beyond the means of the Patent Office. The office is not equipped to carry out such tests.

The state of the art is that there is no art. Without any reference to which growth factors would work and which would not with the specific proteases or vice versa, there

is no way one of ordinary skill in the art to know what would work other than the specific growth factor (KFG) and plasminogen and plasmin taught in the instant specification.

Thus, the claims are unduly broad and do not find proper support from the instant specification. Thus, the rejection is properly made.

Dr. Ni's declaration filed 2/13/2006 has been carefully considered but is not deemed to be persuasive. Even though he argues that one of ordinary skill in the art could test other growth factors related to epithelial cell function and other extracellular matrix degrading protease enzymes besides the KGF (growth factor) and plasmin or plasminogen (the enzyme) this does not address the point at hand. The point at hand was pointed out by applicant's in their brief filed 6/6/2005 on page 13, first full paragraph. That point was that there was non-obviousness between KGF and plasmin or plasminogen. The point was that these enzyme and the growth factor showed synergistic results. Synergism is very specific to particular claimed elements. The fact that there is synergism between a specific growth factor and two specific enzymes does not mean that this synergism is going to be existent between any other growth factors related to epithelial cell function and any other extracellular matrix degrading protease enzymes besides the KGF (growth factor) and plasmin or plasminogen (the enzyme). The specification is very clear about what synergism was shown. This is not a matter about one of ordinary skill in the art knowing which other growth factors related to epithelial cell function and which other extracellular matrix degrading protease enzymes besides the KGF (growth factor) and plasmin or plasminogen (the enzyme) to use since the synergism deals with a synergism tested between the two ingredients used in a

specific incident. Synergism cannot be shown among a class of compounds when only one compound has been shown to have synergism with another specific compound. Simply because one specific compound has synergism with another specific compound does not neccessarily mean that any and all compounds that fall within a given class are all going to behave the same way with another entire class of compounds. The reactions between enzymes and growth factors is simply too unpredictable.

Applicants even in their brief filed 6/6/2005 on page 13, first paragraph, state that "the combination of KGF and plasmin or plasminogen by the Applicants produced unexpected results by behaving synergistically in the treatment of wounds. See Specification, page 19, lines 13-27" and then go on to state in the last paragraph that "Applicants have demonstrated that the protein growth factor KGF is cleaved by protease enzymes trypsin, plasmin, and chymotrypsin in Example 1. See Specification, Page 24, line 1 to Page 25, line 3. This is not an unexpected result. The unexpected result is that the fragment of KGF remaining after the cleavage by plasmin is stable and not significantly degraded in the presence of the enzyme. " Thus, the applicants again and again state that the unexpected results and synergy are with KGF and plasmin or plasminogen and not all of the enzymes and growth factors.

Thus, the declaration while it is noted, does not negate the statements that applicant have made again and again that the unexpected results are with the KGF and the plasmin or plasminogen. It is simply not clear on the record that the unexpected results would be with any and all growth factors and enzymes as claimed only KFG and plasmin or plasminogen. This is because of the unpredicatability in the art when one is

dealing with biotechnology and the fact that applicants themselves have referred to in their own brief the surprising results obtained for the specific KGF and plasmin or plasminogen not all of the growth factors and enzymes encompassed by the claimed subject matter.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael V. Meller
Primary Examiner
Art Unit 1655

MVM